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NO MORE SICK DAYS

— AND —

HOW TO SURVIVE THE FDA's 10 DEADLIEST HUSH-UPS

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Institute

Compiled by the Health Sciences Institute research team.

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Bonus Report 1:

No More Sick Days!

An immune revolution begins: The miraculous protective yeast culture that's been one company's secret weapon for decades

It was a little over two years ago now when executives at a small, family-owned animal feed ingredient supplier in Cedar Rapids, Iowa put two and two together and came up with an answer that's poised to take the supplement industry by storm. And believe it or not, it all started with an outcry from the company's manufacturing plant workers—disgruntled, because they *hadn't* gotten sick. At least, not *nearly* as often as they deserved.

A workweek's worth of perfectly good days off had gone to waste, year after year—and, they insisted, it just wasn't fair.

If you thought this was going to be a losing battle—and, like me, I'm sure you did—you'd be mistaken. In response to what might be the oddest personnel protest in history, the plant workers finally got their way. They'd be able to use those five complimentary days at their own discretion—because, as it turns out, they had a very good point.

As years passed, many administrative and sales employees of the company submitted your typical deluge of medical bills, easily piled up from a bad case of the flu or one of those nasty seasonal sinus infections that it seems like just about *everyone* gets. But

the plant workers? Well, they didn't register so much as a blip on the radar. And because of it, Diamond V's insurance premiums hadn't budged—even while national rates skyrocketed up a colossal 11.2 percent.

Mysterious? Maybe to some. But to Paul Faganel, the unfolding of events was a little less unlikely than anyone might have thought.

Insurance premiums—and debilitating diseases—stopped in their tracks

Faganel, now the president of Embria Health Sciences, was among the first to pick up on the baffling trend. In 2004, he was working on the operations side of Diamond V Mills, with access to the health insurance records, as well as the payroll, which reflected the surplus of unused sick time in question. But it didn't stop with paperwork and insurance premiums—the stories floating around the plant bordered on the unbelievable, too.

Take the plant's manager, for one. Half of a pair of fraternal twins, both he and his sister had been diagnosed with macular degeneration. After 30 years at Diamond V his own vision is still amazingly intact, while his sister's vision has suffered substantially, registering in at only 20 percent—leaving her practically blind. Another longtime employee was diagnosed with multiple sclerosis before she joined Diamond V—and in her 14 years at the plant, the disease has not progressed at all.

The company was riding a stroke of luck that

looked nothing short of heaven sent. But as it turns out, this was a different kind of guardian angel at work: the company's flagship fermented yeast culture. The idea seemed odd, but not unthinkable—after all, the super substance had been keeping farm animals healthy since the family business started in 1943.

Yeast: the secret weapon of farmers everywhere

You probably already know a little something about yeasts. They're single-celled, microscopic fungi, best known for their crucial role in making bread and beer. But you may not have known that farmers have been feeding yeast to animals for years—initially in the form of farm-produced "mash" (maybe the term "slop" sounds more familiar)—only to discover that this unusual food was actually keeping their livestock healthy.

We see it all the time—fermented grapes create wine, for example, which has benefits that compound and surpass those of the grapes alone. Over the course of the fermentation process, mediums such as grains or grapes will take on a whole new nutritional value—becoming enriched with B-vitamins, minerals, amino acids, and other metabolites that are necessary to a sturdy constitution.

But to really get to the bottom of yeast's benefit to Old MacDonald, let's review a few highlights from Farm Feed 101. (Warning—if you already aced this course, you might find these next few paragraphs a little tedious.) Cattle, among the most common of the barnyard animals, are known as ruminants, and their digestive systems are far different from other animals. They have an additional organ, called a rumen, where most of their digestion takes place. Unlike humans, who naturally produce digestive enzymes in their small intestines, a cow's rumen acts as a fermentation vat. The naturally occurring beneficial bacteria living in the rumen produce the necessary enzymes to break down food—especially cellulose, the primary cell wall of green plants (a big part of the cow's diet, for which *no* mammal innately has a digestive enzyme).

Up to 80 percent of the cow's daily requirement for energy results from this fermentation process. That's why including yeast culture in its diet helps encourage the naturally occurring rumen bacteria to do a better job of digesting the cow's food. For this

reason, yeast culture supplementation helps cows absorb more nutrition from the food they eat and produce the maximum amount of high quality milk.

The product that sets Diamond V apart from the pack

Diamond V was founded by a former farmer who saw a market for producing and selling this type of product on a large scale. But more than that, he had a very different method for manufacturing his products—one that, in his experience, was a lot more effective than your run-of-the-mill slop.

According to Faganel, most animal nutrition companies simply mix dry active yeast (similar to what you would buy at a grocery store) into cereal grains as feed. In this case, the yeast cells are young, and though they are still a good source of nutrition (rich in beta glucans, a polysaccharide known to stimulate immune function), they only just begin to ferment by feeding off of the nutrients and oxygen available in the grains. While the fermentation process has started to occur, boosting the nutrient content to a degree, there really aren't any substantial biochemical changes in the feed.

Diamond V, however, was the first to bring the yeast culture to the market, an aromatic granulated substance that contains both the metabolites that result from the fermentation process and the nutrients inside the yeast cells themselves. In their product, the yeast cells achieve full fermentation with a proprietary nutritional medium—the specifics of which are a well-guarded business secret—before they're ever added to the feed.

Mother Nature might be smarter than you think

If it's been a while since you broke out the chemistry books (I know it had for me), the differences here might be looking a little murky. So, I'll do my best to explain the process to you simply. Anaerobic fermentation begins when yeast cells have run out of oxygen and nutrients. When the yeast cells are added directly to a medium, they continue to feed on that—growing and reproducing exponentially—for some time. But as their oxygen and nutrient sources begin to wane, they sense their impending death and begin to secrete a variety of byproducts under the stress of survival—all of which are imparted to the medium, accounting for its fermentation.

In manufacturing their yeast culture, Diamond V lets the yeast cells reach full fermentation in their secret medium first, allowing all of the nutrients to develop completely. Both the cells and the medium are then dried. The result is a complex substance that goes way beyond the typical nutritional profile of regular yeast and contains loads of undefined nutrients.

Those undefined nutrients—birthed by the secret proprietary fermenting medium and preserved by a patented drying process—make this particular yeast culture downright impossible to imitate, as one of literally thousands of unique combinations. As it turns out, Diamond V's products not only work to aid digestion in ruminants like cattle, but they also support the health of other animals—like chickens, pigs, or even fish. And of course, as company executives ultimately discovered, humans are no exception. As consulting director Dr. Stuart Reeves so bluntly put it: “Mother Nature is not stupid.” And it appears that some of her gifts truly are universal.

The ultimate immune modulator that's better than berries at fighting free radicals

Shortly after Diamond V dodged the bullet of mounting insurance premiums, company executives knew it was time to investigate future possibilities. Based on the anecdotal accounts he'd heard, Faganel had been pressing for this all along. Once the paperwork was in place to back up the stories, he knew that they had the makings of a revolutionary product. The first order of business was to conduct a preliminary study to find out what—if any—benefits were actually brewing in the bodies of Diamond V's plant workers.

Ten employees of the manufacturing plant participated in the study, along with a control group of 10 other gender and age-matched subjects that had not been exposed to the company's immune-boosting yeast culture. The study, which included blood and saliva samples from each of the 20 participants, yielded astonishing—though not altogether surprising—results.

The samples of the 10 plant employees exhibited a number of significant differences. Blood tests revealed higher-activity natural killer (NK) cells, despite being lower in their actual numbers. The number of CD-8 (immune suppressor) cells was lower, accompanied by a higher ratio of CD-4 (immune helper) cells. There

were also notably lower levels of the immune complexes that are common culprits behind inflammation and tissue damage. A closer look at saliva samples—to measure salivary IgA, the immunoglobulin that builds a barrier in your body's mucosal tissue—spawned comparable observations. The plant employees had a salivary IgA level that was 68 percent higher than the unexposed study participants.

When researchers looked at the yeast culture itself, it also showed some impressive characteristics. Most notable was its score on the oxygen radical absorbance capacity (ORAC) test, which measures the antioxidant power of any given substance. The yeast culture had a value of 613. That's a formidable number, making such antioxidant powerhouses like blueberries and raspberries pale in comparison—it's a value nearly 300 percent higher than either of those fruits.

Subsequent in-vitro studies and a brief 30-day single-dose study reinforced all of the above findings—and the connection between the yeast culture and a quantifiably heartier immune system moved well beyond the status of mere suspicion. But I wondered: Diamond V's plant workers weren't actually *eating* the stuff. How, then, did they arrive at a recommended human dosage?

Faganel explained that the 500 mg dosage decided upon for each capsule was a pound-per-pound estimate based on the typical effective dosage for other, larger animals. And what was deemed effective for animals was based on over 60 years of research within the feed industry. While tests measuring the particulate matter in the air of the manufacturing plant showed that employees would have ingested only around 10 mg of the yeast per day, Faganel suspects that its positive effects were cumulative—based on daily exposure over the course of at least a decade.

Exhaustive safety studies on the yeast culture also demonstrated that the product is completely non-toxic, won't interfere with drug metabolism, and doesn't cause gene mutation or cell proliferation.

With more concrete proof to support a foray into the nutritional supplement world, Faganel launched Embria Health Sciences. This spin-off is devoted to exploring the vast potential of their parent company's yeast culture on the human health market. Embria's main task—and arguably the most important one—was to hone in on and maximize

the antioxidant and metabolite profile of Diamond V's original yeast culture to maximize its benefit to humans. EpiCor® is the fruit of that labor.

And according to Reeves, now a consulting director at Embria, even more studies are underway to solidify the company's body of evidence, "including a slightly longer term clinical study," he told me, "and an in-house human study."

A preventive approach that upholds lifelong health

This extensive research is one of the many qualities that make Embria's yeast culture unique in its niche of preventive health. But as Faganel points out, the niche itself is enough to set EpiCor apart from the pack. "A lot of the supplements out there are indication-specific," he notes. "But if you take EpiCor when a cold is coming on," he emphasizes, "it's just too late—it won't help."

"It will be about three to four weeks before you'll see any improvements," he told me. "And then you'll notice that if you do get sick, you recover much quicker." According to Faganel, after enough time taking EpiCor, a good night's sleep is usually all it takes to knock out a cold or the flu. And Faganel can vouch for that personally, having benefited from the initial sample capsules that the company has been using in its research. Since his college days, not a year has passed without a sinus infection cropping up like clockwork. But, he tells me, the two years that he's been taking EpiCor have been absolutely free of sinusitis—a shocking feat as, he admits, his overall habits are far from the healthiest.

But there are lots of stories within the company to match his—even from the die-hard skeptics. Faganel told me that the Vice President of Technology Research, a tough-to-convince scientist with a penchant for marathon running, noticed that he stopped getting cold sores after his grueling training sessions—a common occurrence when your body's under unusual amounts of physical stress. When he stopped taking EpiCor, they immediately came back—and, Faganel tells me, the runner was first in line for a refill of his samples.

Another Embria employee broke his arm while waterskiing, severing enough nerves to lose use of his right hand—doctors said there was a chance that he would never regain function. But, to their surprise, he recovered—and fast. When he returned for his six-week follow up, his bone had healed and he had already regained half of the function in his injured hand. His doctor told him that, within six weeks, his body had accomplished six months' worth of healing—and then invited him to participate in a study that he was planning to conduct on a collection of extraordinarily resilient patients.

It's hard not to wonder what kind of impact a product like this will have in an age where antibiotics are handed out like candy and irrational fears of pandemic flu outbreaks abound. One thing's for sure: If EpiCor is even half as effective as all of the stories (and studies) around it suggest, these signs of the times aren't likely to last long.

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EpiCor®, Vitamin Research Products. Ph. (800)877-2447 or (775)884-1300; www.vrp.com.
One bottle of 90 capsules (500mg per capsule) costs US\$49.95 plus shipping.

Bonus Report 2:

How to Survive the FDA's 10 Deadliest Hush-Ups

Deadly Hush-Up No.1: Buffing the Halo

I would be lying if I said I didn't enjoy highly questionable statements made by "experts."

For instance, a recent American Heart Association (AHA) press release carried a quote from a researcher who's also a doctor. In commenting on a study that found non-steroidal anti-inflammatory drugs (NSAIDs) to raise the risk of premature death, he stated: "There is no doubt about the beneficial effects of aspirin among patients after heart attack...and the scientific evidence is undeniable."

No doubt? Maybe he meant to say "plenty of doubt." But I doubt it.

Half in the bag

I'll back up a little bit.

The study mentioned above comes from a university hospital in Copenhagen, Denmark. Researchers evaluated medical records of more than 58,000 heart attack patients. The records were matched against prescriptions for COX-2 inhibitors and NSAIDs that were filled by the patients after their heart attacks. (The seven-year study period ended in 2002, so Vioxx was among the COX-2 inhibitors used—long

before it was taken off the market in 2004.)

After assessing the risk of a second heart attack or death by any cause, researchers found that patients taking these medications had a "strikingly higher risk of death" within the study period compared to heart attack patients who didn't use the drugs. Furthermore, higher doses of the drugs were associated with an even higher risk of death.

But there was a curveball in the results: Use of COX-2 inhibitors or NSAIDs didn't increase the risk of a second heart attack. According to the AHA press release (the study hasn't been published yet), researchers are now examining death certificates to assess the different causes of death.

Hmm...wouldn't that have been the obvious thing to do BEFORE they started reporting on the results?

Evidence denied

Besides the fact that other studies have shown that Vioxx and (to a lesser extent) other COX-2 inhibitors increase heart attack risk, there was yet another curveball in the study: Aspirin intake wasn't assessed.

Aspirin is probably the most widely used NSAID. But according to Gunnar H Gislason, M.D., the lead author of the study, the absence of aspirin data is not a factor. Why? Because according

to Dr. Gislason (let's look at his quote again):
"There is no doubt about the beneficial effects of aspirin among patients after heart attack...and the scientific evidence is undeniable."

Not so fast, Doc.

In the *e-Alert* "Double-Edged Wonder" (7/14/04), I looked at a UK study that examined the use of aspirin and prescription blood thinner (warfarin) in about 280 patients who had suffered either heart attack or stroke.

After an average follow up period of more than two years, neither the aspirin nor the warfarin provided any greater protection against death, nonfatal stroke, or nonfatal heart attacks than a placebo. Subjects who received aspirin therapy, however, were nearly *twice as likely* to suffer a heart attack or stroke as were those who took warfarin or placebo. Gastrointestinal problems were also elevated in the aspirin group.

In an interview with Reuters Health, the lead re-

searcher of the study, Dr. John G. F. Cleland, stated that any theoretical benefit of using aspirin after a heart attack "is outweighed by real evidence of harm."

Freshly buffed halo

Not too long ago a new aspirin study was published in the *Journal of the American Medical Association*. The study found that women apparently receive modest stroke protection from aspirin therapy, but little cardiovascular protection. The opposite is true for men.

Of course, the media reports about this research treated aspirin's saintly status as a given, furthering the 20th Century myth that this drug somehow works miracles with no side effects.

Tell your family and friends: Aspirin is a drug. And while it may have its place, it should be used just as you would use any drug: with caution.

Deadly Hush-Up No. 2: Formula for Disaster

I feel betrayed. But it's my own fault."
That comment comes from a colleague of mine named Lou who sent me an e-mail with some enlightening (and frightening) information about foods that contain soy.

Lou writes: "When my son was born about 13 years ago my wife wasn't able to breast feed (long story), so we looked at the various formulas available and decided on one that had a soy base. Back then we were convinced that soy was healthy. Looking back now I want to kick myself. I dumbly accepted the soy-is-healthfood sales pitch without ever really questioning it.

"I've attached some items about a study that was a real eye opener for me and my wife. Maybe your readers will find this info useful and avoid our mistake."

Minimized consumption

According to an article in *Mothering* magazine (one of several articles Lou sent), researchers with the Israeli Health Ministry spent about a year assessing a wide variety of soy studies. The research team included more than a dozen nutritionists, pediatri-

cians, and oncologists. They announced their findings last summer.

The primary conclusions:

- Estrogen-like plant hormones (isoflavones) in soy may increase the risk of health problems, including breast cancer and reduced fertility in men
- Evidence that soy reduces symptoms of menopause is inconsistent
- Soy may slightly reduce cholesterol levels, but no clear link to a reduced risk of heart disease was found

Researchers "strongly urged" minimized consumption of soy foods until further studies are able to demonstrate soy's safety. In addition, the Israeli team recommended that soy baby formula should be used only as a last resort in cases where infants can't be breastfed and cow's milk can't be given.

Another article Lou sent referred to a study that especially concerned him. It was an animal study in which newborn male monkeys were fed a soy formula. Researchers concluded that soy impeded the normal testosterone production that occurs in the first months of life.

Heart & soy

This week I returned Lou's favor when I sent him some additional information about soy.

The first item is an oldie that appeared in the March 1999 issue of *Natural Health*. In that article, author Sally Euclaire Osborne cited a New Zealand study that examined the isoflavone levels in soy formula for babies. The recommended daily intake of the formula was found to be *four times* the amount capable of changing the reproductive hormones in women.

The second item brings us up to date with new information just released by the American Heart Association (AHA).

In 2000, the AHA recommended soy consumption based on studies that indicated soy had a cholesterol-lowering effect. But when further research began to contradict those findings, the AHA launched a review of more than 20 soy studies. Results showed that soy protein has no effect on HDL cholesterol, and a very small effect on LDL cholesterol. In addition, researchers concluded that soy does not reduce hot flashes and other menopausal symptoms, nor does it prevent prostate, breast, or uterine cancer.

In an Associated Press (AP) article that covered the AHA study, several pro-soy doctors and experts weighed in, minimizing the results of these new findings. One clinical nutrition professor told the AP that even though soy isn't a "magic bullet" it can still be "a valuable contributor to a heart-healthy diet."

STOP IT ALREADY! Soy is not health food!

Normally I'd be bucking the mainstream and endorsing an alternative food product that enhanced health. But soy is not on the alternative fringe. Anything but! Thanks to the aggressive marketing efforts of soybean producers such as Monsanto and Archer Daniels Midland, soy has won a mainstream reputation as a nutritional medicine of sorts, even though evidence to the contrary has been steadily mounting for years.

If you like soy, try to limit your intake to soy products developed from fermented soy. (HSI Panelist Allan Spreen, M.D., explains the importance of soy fermentation in the *e-Alert* "Adult Swim" 4/16/03.)

Personally I'm afraid of a plant that can be processed into a substitute for everything from tuna fish to chocolate pudding.

Deadly Hush-Up No. 3: Messing With Your Head

Every time I see a gaggle of smokers standing around the entrance to an office building I feel profoundly grateful that I'm not out there with them.

I used to be one of them—a slave to the habit. And without question, quitting cigarette addiction was the healthiest thing I've ever done. It was also one of the *hardest* things I've ever done. And I know I wouldn't have succeeded without the daily support of my husband.

But my husband can't be there to help everyone stop smoking, so I guess that's why Pfizer developed Chantix—only the second smoking cessation drug with FDA approval that doesn't use nicotine.

No nicotine—that sounds good. But after reading the details (and reading between the lines), you might wonder why any clear-thinking person would choose this regimen over a non-pharmaceutical method.

The old switcheroo

Before we look at Chantix (holding it at arm's length so we don't get any on us), I'll tell you a little secret about that other FDA-approved non-nicotine smoking cessation drug.

It's called Zyban and it's been on the market since 1997. But its active ingredient has actually been around quite a bit longer, going by the name Wellbutrin, an antidepressant that has a history of increased seizure risk when used in high doses, according to the National Alliance on Mental Illness. You have to wonder how many smokers out there are trying to quit by using Zyban, completely unaware that they're actually taking a powerful antidepressant.

Ah, but there's more. The Zyban information flyer warns: "Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior." And according to the Wellbutrin website, the "most common side effects" with Wellbutrin XL include skin rash, sweating, stomach pain, anxiety, dizziness, trou-

ble sleeping, nausea, sore throat and fast heartbeat.

Classic! The cure might be worse than the habit.

In the pleasure center

Nicotine binds to certain brain receptors, prompting a release of dopamine in the brain's pleasure centers. This creates the sensation that cigarette smokers chase relentlessly. Chantix binds to the same brain receptors, blocking the nicotine and the pleasant sensation. The drug also cuts cigarette cravings by slowing dopamine release.

Studies show that this method works on a little over 20 percent of smokers who take Chantix for a year. Only 16 percent of Zyban users were successful over the same test period. And Chantix was even more effective in a 12-week test, although the subjects' long-range success in quitting for good was not monitored.

And of course, there were side effects. Pfizer has put up a Chantix website that lists these side effects as the most common: nausea, constipation, gas, vomiting and changes in dreaming. (I wonder if "changes in dreaming" is a sly euphemism for "nightmares.")

But that list just gets things started. There are quite a few side effects listed as "frequent," including diarrhea, gingivitis, chest pain, back pain, dizziness, anxiety, depression, emotional disorder, polyuria (excessive

urination), menstrual disorder and hypertension.

And then there's this intriguing note: "Fewer than 1 out of 1,000 patients reported euphoria in clinical trials with Chantix." Euphoria? Hmm...sounds like a little dopamine might be slipping through to the pleasure centers for a few blissfully happy Chantix users.

Creating an aversion

In the *100 Greatest Cures* special report, we told you about a botanical called Plantago Major. About 15 years ago, Dr. Mary Cody, a physician and researcher, found that Plantago Major creates a natural aversion to tobacco when inhaled or ingested.

In a 1992 study, 24 heavy smokers were given Plantago Major tincture in a nasal spray and then instructed to smoke. More than 80 percent of the subjects reported an aversion to tobacco shortly after receiving the dose, and the effect lasted as long as 24 hours for some of the subjects.

Dr. Cody's Plantago Major formula was patented shortly after that trial and is now available as a product called CIG-NO, which is sprayed under the tongue and creates an almost immediate reduction in cigarette cravings, with no reported side effects. You can find more information at cigno.com.

Deadly Hush-Up No. 4: Carbon Monoxide in Our Food?

For the moment, let's forget that carbon monoxide is a poisonous gas. And let's also ignore the fact that pumping a small amount of carbon monoxide into a package of meat is supposedly safe.

Now why in the world (you might ask) would anyone even *think* of adding carbon monoxide to a package of, say, ground beef? Simple: When carbon monoxide interacts with meat pigments, the pigments do something interesting—they stay nice and red much longer.

So let's forget the poisonous gas part. Let's pretend that instead of a poisonous gas, carbon monoxide is as delightful and toxin-free as a spring breeze. If that were true, adding carbon monoxide to meat would still be a really bad idea for one reason: When meat stays red, consumers can be fooled into thinking old meat is fresh.

But of course carbon monoxide *is* a poisonous gas. Even so, the FDA thought it would be a splendid idea to add it to meat products.

As I told you in the *e-Alert* "Live For the Moment" (3/1/06), in 2004 the FDA approved the use of modified atmosphere packaging (MAP), which uses a variety of gases to help preserve meat and, in the case of carbon monoxide, keep the meat looking fresh. That was one year after the European Union banned the use of carbon monoxide because a review panel thought the practice would deceive customers and expose them to unsafe meat.

Oh...and one more thing...you'll never know if you're buying MAP treated meat because the FDA doesn't require manufacturers or stores to alert consumers when this process is used.

Food Product Daily reported that the Committee on Agriculture in the U.S. House of Representatives is "mulling over" a proposal that would ban the use of

carbon monoxide in meat packaging.

Mulling it over! Wow—I feel less toxic already!

In a February 2006 article, *The New York Times* noted that the A&P and Pathmark grocery chains had already stopped using MAP treated meat. Imagine that—someone with good sense at both of those chains recognized a bad idea and rejected it, even though it had the FDA stamp of approval.

Deadly Hush-Up No. 5: RADAR Detector

Out with the new...in with the old. A large majority of consumers would prefer to take a drug that's been on the market for 10 years or more before trying a newer drug, according to a recent survey conducted by Medco Health Solutions.

You have to wonder; Would that same survey have had a completely different outcome five years ago, or even one year ago? In the past few months we've seen some best selling drugs crash and burn amid safety concerns, while major drug companies and the FDA have taken hit after hit in the mainstream media.

But at exactly the time the FDA could use a complete image makeover, agency executives made an astonishing decision.

Hit and miss

What's the primary job of the FDA? To insure food and drug safety, right? And how is that done? In the case of drugs, FDA executives rely on drug companies and doctors to report adverse reactions. This information is compiled in an FDA database. But gathering the information is only the first step. In some cases it takes several years to analyze the data in order to recognize and respond to a proven adverse reaction.

Under this system drug companies are basically being asked to police themselves. (That would be like asking Tony Soprano to, pretty please, not have anybody "whacked.") But relying on reports of adverse reactions from doctors is also undependable. M.D.s are expected to report adverse reactions on a voluntary basis. But the process is time consuming and in some cases doctors may fear that investigations will

If you don't like the idea of eating meat treated with carbon monoxide, talk to the manager of the meat department in your local grocery. Ask him if he sells meat with modified atmosphere packaging. If the answer is yes, let him know you're going elsewhere to purchase meat products. That's how a bad idea gets changed. We don't have time to wait for Congress to mull it over.

draw malpractice suits.

By some estimates more than 90 percent of all adverse reactions go unreported. And yet, according to the *Chicago Tribune*, the FDA receives as many as 400,000 yearly reports of adverse reactions, and the worst of these reactions account for about 100,000 deaths each year.

RADAR network

About five years ago, Northwestern University researchers Charles L. Bennett, M.D., Ph.D., began building a better radar to detect adverse reactions to drugs. In fact, he called his project RADAR: Research for Adverse Drug Events and Reports.

Dr. Bennett's process is fairly simple. Twenty-five doctors from five U.S. cities report their observations of potential adverse reactions, with special interest paid to the most serious reactions that could be fatal. When reports come in they're then sent out to a larger group of researchers who begin to hunt for other reports. The FDA post-marketing database is one of the sources used for additional reporting.

To date, 16 different drugs and medical devices have been linked to adverse reactions that are potentially fatal. RADAR has identified severe adverse reactions in nearly 1,700 patients, and 10 percent of those patients died of complications associated with the reactions.

So has the FDA embraced Dr. Bennett's RADAR? If you guessed "no" to that question, you're on the right track. But even hardened cynics might be surprised at what happened next.

The big dog bites

One of the drugs that RADAR examined was Plavix, a popular clot-prevention drug. According to the *Chicago Tribune*, Dr. Bennett's researchers reported that in rare cases Plavix may trigger a "catastrophic col-

lapse of the blood system.” At Dr. Bennett’s urging the FDA added a warning to the drug packaging.

Dr. Bennett followed up the Plavix research with a study that compared how four years of adverse reactions to Plavix were tracked by the FDA, Bristol-Myers Squibb (BMS, the makers of Plavix) and the RADAR team. As reported in the February 2004 issue of the journal *Stroke*, Dr. Bennett scored RADAR’s effectiveness at 92 to 100 percent, while BMS scored between 8 to 58 percent and the FDA scored zero to 23 percent. Dr. Bennett gave the FDA a failing grade.

The FDA’s response? Apparently, someone at the agency was not very pleased. The *Tribune* reports that FDA officials reacted to the *Stroke* study by terminating Dr. Bennett’s access to the agency’s database.

The 16 to watch

In 2005, the *Journal of the American Medical Association* published the RADAR conclusions of Dr. Bennett and his colleagues. The study included a list of these 16 drugs and medical devices that have produced adverse effects: Zolendronate, Amiodarone, Epoetin, Thalidomide, Gercitabine, Ticiopidine, Gerntuzumab, Clopidogrel, Nevirapine, Flutamide, Sirolimus-eluting cardiac stent, rHu-MGDF (for thrombocytopenia), Bicalutamide, Enoxaparin, rHu-MGDF (for lymphomas), Paclitaxel-eluting cardiac stent.

If you’re currently using any of these drugs or devices, or if you know someone who is, it would be wise to talk to your doctor about the potential risks. But make sure he’s not relying on the FDA’s data.

Deadly Hush-Up No. 6: Wake Up, Joe

Let’s say you’re a drug company executive. That’s right—you’ve got piles of money that would make Donald Trump blush like a smitten schoolgirl.

Now let’s say you devote millions to the development of a drug that starts to get a reputation for safety problems even before it’s submitted to the FDA for approval.

And let’s say that further down the line the FDA discovers instances of fraud in a major safety study of your drug. In fact, you turn on NPR one morning to hear that the doctor who enrolled the largest number of study subjects was sent to prison for fabricating false data about the study!

That would seem to be plenty enough to doom a new drug right there. But the bad news isn’t over yet. Let’s say on another morning you open up *The New York Times* to read this: An FDA report concludes that when representatives of your company became aware of safety problems they didn’t inform the FDA, but the agency later discovered that little indiscretion on its own.

With all these revelations flying, you’ve got to figure your drug will never see the light of day, correct?

Well...not exactly.

As an HSI member, you actually do have some-

thing in common with a drug company executive: Unlike the Average Joe who still believes the FDA rigorously protects consumers from unsafe medications, you have a good idea how this outrageous story will play out.

Who could have predicted?

The drug company is Sanofi-Aventis and the drug is telithromycin, better known by its brand name: Ketek.

Ketek is an antibiotic that treats bacterial infections associated with sinusitis, bronchitis, and pneumonia. After the safety concerns and outright fraud described above, was it approved by the FDA? Of course it was! And now—two years after approval—some ugly chickens have come home to roost.

Here’s the latest box score for Ketek adverse effects, according to a 6/29/06 Reuters report:

The FDA has received 12 reports of acute liver failure linked to Ketek. Four of those patients died. One patient required a liver transplant.

So, of course, the FDA response was swift and the drug was immediately taken off the market. I mean, getting rid of a sinus infection isn’t worth risking acute liver failure, right? It’s not like this is the cure for cancer, after all.

Well, that’s the response the Average Joe might expect. Actually, the FDA simply announced that Sanofi-Aventis decided to add a new warning to the drug’s information flyer.

Don't you feel safer already?

Loss of consciousness

Sanofi-Aventis execs and FDA officials may have thought this scandal was going to quietly go away, but a June 2006 *New York Times* report exposed a heated Ketek debate going on behind the scenes at the FDA.

The *Times* states that liver failure has occurred in 14 patients, and 23 others experienced serious liver injury. The *Times* also notes that Ketek may cause blurred vision and loss of consciousness. So it's no surprise really that *someone* at the FDA was up in arms about this drug.

That someone is Dr. David Graham, associate science director of the FDA's Office of Drug Safety. As I've noted in previous *e-Alerts*, Dr. Graham's opinions have frequently run contrary to official positions of the agency, and the Ketek problem is a perfect example.

The *Times* piece quotes from e-mails written by Dr. Graham: "We don't really know if the drug works...and we're flying blind as far as safety goes."

He also notes that FDA adverse drug reaction data on Ketek suggests that the drug is "uniquely more toxic" than most other drugs.

Yikes! Not just toxic, and not just more toxic, but *uniquely* more toxic! That's got to be a new low in characterizing a drug.

So why is Ketek even on the market? Dr. Graham: "It's as if every principle governing the review and approval of new drugs was abandoned or suspended where telithromycin is concerned."

After reading that, if there's an Average Joe out there who still believes the FDA is a guardian of safety, he can at least take a tiny shred of comfort in this news: The *Times* reports that when an FDA safety official called on Sanofi-Aventis to stop testing Ketek on children with ear infections, the company announced a "pause" in pediatric clinical trials.

A pause! Obviously they're going all out to ensure (the appearance of) safety.

Deadly Hush-Up No. 7: Taken for a Ride

Not too long ago, I read a news article about the FDA that is so completely ridiculous I had to read it twice to make sure I wasn't missing something.

I wasn't. It's insanely ridiculous. And the subject of this recent *Washington Post* (WP) article would be hilarious if only it didn't have the potential to negatively impact the health of nearly every U.S. citizen.

Who let these guys in?

There's a public health issue in this country that borders on scandal: The overuse of antibiotics—among humans and animals—is creating greater and greater antibiotic resistance. You, me, your family, your neighbors—all of us, little by little, are developing resistance to the best antibiotics out there.

For instance: About 10 years ago, an FDA-approved animal antibiotic known as Baytril (made by Bayer Corp.) was linked to microbial resistance in humans. When the FDA tried to ban Baytril, Bayer put up a fight that lasted years.

To avoid further problems like this, the FDA brought together representatives of the public health community to establish guidelines for evaluating new animal drugs and the potential impact on humans. The result was an official checklist called Guidance for Industry #152. But according to the WP article, drug companies pressed hard to influence the checklist, and the final guidelines tilt in favor of—guess who?—the drug companies!

Now...let's watch Guidance #152 in action...

Authority figure

The FDA is currently considering the approval of cefquinome, a powerful animal antibiotic that happens to be in the same class of drugs that provide humans with what's known as a "medicine of last resort." One of the medicines in this class is effective against several human infections that are otherwise nearly impossible to treat. It's also the only drug that effectively treats the most severe infections among cancer patients.

How great is the fear that cefquinome use might lead to the loss of this last resort? In September 2006, the American Medical Association lobbied against

cefquinome's approval, and the advisory board convened by the FDA voted to reject approval, largely based on two factors: 1) The likelihood that human microbial resistance may develop, and 2) The fact that there are already more than a dozen effective medications that address the cattle respiratory disease that cefquinome is designed to treat.

After the advisory board's vote, Stephen Sundlof, head of the FDA's Center for Veterinary Medicine, dismissed it, describing it as "non binding." He added that Guidance #152 would provide the basis for safety decisions. So the FDA is expected to approve cefquinome, thanks to G #152, which places the bar very high for proving the dangers of a new drug.

Meanwhile, the advisory board also suggested that if cefquinome was approved, the FDA should require InterVet Inc. (the maker of the drug) to sup-

ply details about the distribution of cefquinome so that patterns of human resistance could be compared to patterns of the drug's use.

You know—for *safety*. General welfare. That sort of thing.

Here's the exact wording from the *Washington Post*: "But Sundlof offered little hope for that outcome. 'That is information that would be useful to have,' he said. But the agency does not have the authority to demand it."

In my entire life I've never read a statement more stupefying than that one!

The agency doesn't have the authority? The agency *is* the authority! Well, that's the way it's supposed to work. Maybe Mr. Sundlof assumes we'll read between the lines and understand that drug companies keep the agency's "authority" on a very short leash.

Deadly Hush-Up No. 8: The Olestra Experiment: How Does it Feel to be Treated Like a Lab Rat?

You've probably already heard of the "break-through" fat substitute called Olestra. It's the dieter's dream come true! Eat all the potato chips, cheese puffs, and tortilla chips you want—they're now *fat-free* and just as delicious!

The FDA has approved Olestra, even though it not only causes diarrhea and cramping but also depletes the body of important cancer-fighting nutrients. In order to monitor the long-term effects of Olestra, the FDA has restricted it to certain snack foods. These foods, which will contain a warning label, will be tracked by the FDA to see

if Olestra is safe enough to be used more widely.

In other words, this is a colossal experiment: a nationwide study capable of turning all 269 million Americans—including you—into guinea pigs.

In an effort to modify public opinion about the negative effects of Olestra on one's health, Proctor and Gamble (the manufacturer of Olestra) recently sponsored a study that examined its effects when consumed in minute amounts. The results? If you eat just one bag of Olestra chips, you'll have less diarrhea and cramping than if you eat larger amounts. Perhaps, like us, you find these conclusions less than reassuring.

And that's just the beginning of the plastic foods and fad diets that will threaten your health in the years to come—foods that may cause bone loss, clogged arteries, and even tumor growth!

Deadly Hush-Up No. 9: Word Fail

I think I need to get a punching bag for my office. Or maybe I'll take up kickboxing. I know this much, I'm going to have to do something to vent the perpetual aggression I'm beginning to develop from reading too many articles about mainstream medicine.

Today's topic goes beyond infuriating. When I

asked my Microsoft Word to help me out with some synonyms for infuriating, it suggested maddening, annoying, irritating, exasperating, and galling. Sorry, Word—that doesn't even begin to cover it.

This you won't believe

On a situation I've been following that has only gone from bad to worse. Here's an update: It's now officially moved on to "worst."

First the bad: In the *e-Alert* “Get Up and Go” (3/27/07), I examined a stunning revelation from the FDA that there is no evidence that Procrit (and other erythropoiesis-stimulating drugs which are used to treat anemia) reduces fatigue, increases energy, or improves quality of life for cancer patients undergoing chemotherapy or radiation.

And worse: The FDA also warns that misuse or overuse of these drugs may produce dire results, such as accelerated tumor growth in head and neck cancer, risk of blood clots in patients with kidney failure, and shortened time to death when given to patients not on chemo.

And now for the absolute worst: The companies that make these drugs actually pay generous sums to doctors who administer the intravenous medications in their clinics. Not only is this completely legal, but it also encourages the use of higher doses, and higher doses increase the risk of heart attack and stroke.

How's that again?

You might wonder if you read that right: Drug companies can actually pay doctors to use their drugs? Amazing (and infuriating!) but true.

So how do they get away with it? Easy: rebates.

According to a *New York Times* report, it's all about who buys the drugs. If a doctor prescribes a drug for a patient to purchase, federal law prohibits a drug company from paying the doctor a little kick-back for each prescription. But if a doctor runs a cancer clinic or a dialysis center where patients are administered drugs intravenously, then the doctors

are the ones who purchase the drugs. In that case, the law allows a drug company to offer rebates on the cost of the drugs.

But wait—it gets worse. No only do doctors receive rebates, but the *Times* notes they also receive reimbursement from private insurers or Medicare. And these reimbursements are often marked up over the price doctors pay for the drugs. In addition, the more drugs purchased, the higher the rebates, and rebates climb higher still when a doctor agrees to use just one company's drugs.

A sweet racket

If your ability to feel infuriated, exasperated, and annoyed has just about reached its safe upper limit, please read no further because once again we're about to go from worse to worst.

As you might suspect, the rebate program has given sales of this class of drugs a hearty boost. The *Times* reports that dialysis patients in the U.S. tend to get doses that are more than twice as high as the average for dialysis patients in Europe. And U.S. cancer patients are about three times more likely to be given these drugs compared to European cancer patients.

Of course, not all oncologists and dialysis centers are riding on this gravy train, but those who do are making a tidy profit. The *Times* notes that one U.S. practice consisting of six doctors prescribed \$9 million worth off the anemia drugs last year. Their rebate: \$2.7 million.

Excuse me. I have to go out and buy a punching bag.

Deadly Hush-Up No. 10: Spice Wreck

I'm not sure what makes me angrier—the fact that dangerous trans-fats are everywhere in our food supply, the fact that FDA officials pretend to do something about trans-fats but really do very little, or the fact that the FDA has actually gone out of its way to demonize saturated fats and dietary cholesterol by tying them to trans-fats, as if the comparison were perfectly natural.

These guys never cease to infuriate me!

Hiding in plain sight

While shopping the other day I checked the ingredients label on a bottle of mixed black and red pepper. (I'm allergic to garlic, so I have to check labels to make sure it's not hidden in the mix.) What was hidden in with the pepper came as a shock: partially hydrogenated oil. In other words: trans-fats! I expect to see the word “hydrogenated” on packaging for baked goods, crackers, chips, etc.—but ground pepper?

I recently read an FDA report on trans-fats that included this unsettling fact: The average daily trans-fat intake for American adults is 5.8 Grams. Nearly six grams per day! And if we're even picking

up trans-fats in spices, it's no wonder we're getting so much of this deadly junk in our diets.

And how much is too much? According to the FDA: "While scientific reports have confirmed the relationship between trans-fat and an increased risk of CHD (coronary heart disease), none has recommended an amount of trans-fat that the FDA could use to establish a Daily Value."

That's 100 percent partially hydrogenated hogwash.

In previous *e-Alerts* I've talked about a 2002 report from a National Academy of Sciences panel that attempted to set a safe intake level for trans-fatty acids. The panel's conclusion: "The only safe intake of trans-fat is zero."

Hello? FDA? This is the National Academy of Sciences calling. We've had your Daily Value of trans-fats ready for five years now. You can drop by and pick it up at any time.

FDA math grade: F

The FDA report on trans fats does two very annoying things.

1) It requires food manufacturers to note the trans-fat content in every product that contains more than half a gram of trans-fats per serving. Any product with less than 0.5 grams per serving can claim "zero trans-fats."

This is a classic bait-and-switch, and you have to imagine that one of the reasons our average daily intake of trans-fats is unacceptably high is because there are so many products with "No trans-fats!" prominently displayed on the packaging, when in many cases that's completely false. "No trans-fats" should mean none, not "less than 0.5 grams of trans-fats per serving."

2) The report demonizes saturated fat and cholesterol by lumping them together with trans-fats. Quote: "Consumption of saturated fat, trans fat, and dietary cholesterol raises low-density lipoprotein (LDL)...which increases the risk of coronary heart disease."

Humans have been consuming saturated fats and cholesterol for eons. They're natural components of

our diets. Trans-fats, on the other hand, are the byproducts of oil processing. They're not natural, they're completely man-made, and they're very dangerous (linked to cancer risk as well as heart disease).

Of course, the FDA—the Big Kahuna of mainstream nutrition—must always give the impression that saturated fats and dietary cholesterol are the primary sources of heart disease. With this report, it almost seems as if FDA officials are thinking: "Okay, if we have to recognize the dangers of trans-fats, then saturated fats and cholesterol are going down with the ship."

On the level

If the FDA and other mainstream powers-that-be have convinced you that saturated fats and dietary cholesterol really should be considered just as dangerous as trans fats, consider this quote from the March 2006 issue of *The Douglass Report* Newsletter:

"Last year, the *American Journal of Clinical Nutrition* published a review of saturated fat studies from the Department of Food Science and Technology at the University of California. The authors concluded that reducing saturated fat does not prolong life or lower the incidence of coronary heart disease. The UC authors wrote: 'The conclusion of an analysis of the history and politics behind the diet-heart hypothesis was that after 50 years of research, there was no evidence that a diet low in saturated fat prolongs life... Overall, dietary intervention by lowering saturated fat intake does not lower the incidence of nonfatal coronary artery disease; nor does such dietary intervention lower coronary disease or total mortality.'"

And in another issue of *The Douglass Report*, Dr. William C. Douglass II takes on margarine, which is a partially hydrogenated nightmare: "Margarine dramatically increases the risk of coronary heart disease as compared to butter. In fact, according to a 1999 study published in the *New England Journal of Medicine*, eating margarine can increase heart disease in women by 53 percent over eating the same amount of butter."

I honestly don't expect the FDA will ever level with the public about the real dangers of trans-fats or the truth about saturated fats and dietary cholesterol.

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